DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Tracking Form for Applicants for New Technology Add-on Payments under the Acute Inpatient Prospective Payment System (IPPS)

1. Technology Name:

   Cardiac Resynchronization Defibrillator Systems

2. Manufacturer Name:

   Medtronic, Inc

3. Trade Brand of Technology:

   InSync® Defibrillator Systems, which include:
   InSync ICD Model 7272
   InSync Marquis Model 7277
   InSync II Marquis Model 7289

4. Brief Description of Service or Device:

   Cardiac resynchronization therapy, also known as CRT or bi-ventricular pacing, is a new and innovative therapy designed to treat cardiac ventricular dysynchrony, which is common in about 15-20 percent of patients with heart failure. The technology is designed to coordinate the beating of the chambers of the heart in a way that enhances the heart's pumping efficiency. Combined CRT-ICD technology (or CRT-D) enables optimal therapy for symptoms of congestive heart failure and optimal protection from fatal ventricular arrhythmias by combining the capability of two therapeutic devices into one.

New Criteria

Note: To qualify for a new technology add-on payment, the technology or service must not be reflected in the data used to establish the diagnosis related groups (DRGs).

5. Date of Food and Drug Administration (FDA) approval (or expected approval) for the device or service:

Component	Name of Device	FDA Approval Date
Defibrillator Device	InSync ICD Model 7272	June 26, 2002
	InSync Marquis Model 7277	March 27, 2003
	InSync II Marquis Model 7289	July 21, 2003
LV Lead	Attain LV Model 2187	August 28, 2001
	Attain (CS/CV) Model 2188	August 28, 2001
	Attain OTW Model 4193	May 2, 2002

6. Does the technology have an International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) procedure code(s) or is an application pending?

   a. If yes, please provide the ICD-9-CM procedure code(s) used to identify the clinical procedure(s) with which the medical service and technology is used.

A request for unique ICD-9-CM procedure codes was presented to the ICD-9-CM Coordination and Maintenance Committee on November 1, 2001. Unique codes were requested and recommended by the committee. These codes were approved and became effective October 1, 2002. The codes specific to CRT-D systems are:

ICD-9-CM Procedure Code	Description
00.51	Implantation of cardiac resynchronization defibrillator, total system [CRT-D]
00.52	Implantation or replacement of transvenous lead [electrode] into left ventricular coronary venous system
00.54	Implantation or replacement of cardiac resynchronization defibrillator pulse generator only [CRT-D]

   b. If there is no existing ICD-9-CM code that captures this new technology, please indicate whether you will be applying for a new code. (Refer to http://www.cms.hhs.gov/paymentsystems/icd9 for more information.)

7. Have you submitted an application for outpatient pass-through payments under the Medicare outpatient prospective payment system? If so, please provide the tracking number or, if it was approved, please provide the date of approval. (Please refer to http://cms.hhs.gov/providers/hopps/apc.asp for more information.)

Outpatient applications for pass-through payments were submitted in December 2001 for the CRT-D device and the left ventricular lead. CMS rejected the request for a pass-through code for the CRT-D device because a code, requested by another manufacturer, had been in effect since 1999, during the clinical study period. CMS did however, allow a unique pass-through code (C1900) effective July 2002 for the left ventricular lead(s). The C code should be in effect during the 2-3 year counting period as designated by CMS.

Cost Criteria

Note: To qualify for a new technology add-on payment, the technology or service must result in average charges for cases using the technology in excess of 75 percent of one standard deviation above the average charges for the DRG(s) to which the technology or service is assigned.

Provide the following information to demonstrate the technology or service meets the criterion.

8. What is the anticipated average standardized charge per case involving this new technology? For details how to standardize charges please refer to the technical appendix of the application form.

   Proprietary information provided in the application to CMS.

9. What is the total estimated cost per case for the service or technology (this will include all costs involved in the case, including the cost of the service or device)? What is the cost of the technology per patient? Please provide a breakdown how the cost of the technology is calculated (i.e. **Drugs**- Average dosage or number of units per patient (ml/kg/hr); **Devices**- breakdown of the cost of all components used in the new technology).

   Proprietary information provided in the application to CMS.

10. List the diagnosis-related groups (DRGs) to which cases involving this new technology will most likely be assigned.

Effective October 1, 2003, the following DRGs are applicable to CRT-D:

CRT-D DRGs	
DRG	**Description**
515	Cardiac Defibrillator Implant Without Cardiac Catheterization
535	Cardiac Defibrillator Implant with Cardiac Catheterization and With Acute Myocardial Infarction, Heart Failure, or Shock
536	Cardiac Defibrillator Implant with Cardiac Catheterization and Without Acute Myocardial Infarction, Heart Failure, or Shock

11. What is the anticipated volume of Medicare cases involving of this technology (by DRG)?

We estimate that there are approximately 12,000 Medicare beneficiaries who will be implanted with a Medtronic device in the coming year, although we are uncertain of the volume by DRG. CMS data has indicated that approximately 19% of Medicare discharges for defibrillator implants are performed without a cardiac catheterization (EP study) at time of admission. From this we could estimate that approximately 19% of the CRT- D Medicare cases would be assigned to DRG 515. With the remaining 81% of Medicare cases, it would be difficult to estimate the percentage of cases falling into DRG 535 or 536. This will be better understood in the future once a baseline of data is established.

Clinical Improvement

Note: To qualify for a new technology add-on payment, the technology or service must represent a substantial clinical improvement over existing technologies or services

12. Please provide a short synopsis of the following clinical issues added to the new technology. Use the regular application to submit full details.

    a. Briefly describe how the new service or technology represents a substantial clinical improvement over existing services or technologies:

A substantial body of published research finds the therapy:

- Improves clinical outcomes affected by chronic heart failure, most notably symptoms, quality of life, exercise tolerance, and hemodynamic performance.
- Reduces hospitalizations due to chronic heart failure, in terms of both the number of admissions and the length of stay.
- Reduces mortality from chronic heart failure. A meta-analysis of data from four clinical trials found that CRT reduced mortality from chronic heart failure by 51% during 3- to 6-month follow-up periods. We understand additional findings on mortality from the COMPANION study will be published in early 2004.

    b. List of published peer-review articles relevant to the new service or technology.

The following is a list of publications enclosed with the New Tech application. A bibliography, also enclosed with the application, lists additional publications.

1. Abraham WT, Fisher WG, Smith AL, et al for the MIRACLE Study Group. Cardiac resynchronization in chronic heart failure. *N Engl J Med* 2002; 346:1845-1853

2. Betts TR, Allen S, Roberts PR, Morgan JM. Inappropriate Shock Therapy in a Heart Failure Defibrillator. *Pacing Clin Electrophysiol* 2001;24:238–240

3. Bradley DJ, Bradley EA, Baughman KL, Berger RD, Calkins H, Goodman SN, Kass DA, Powe NR. Cardiac resynchronization and death from progressive heart failure: A meta-analysis of randomized controlled trials. *JAMA* 2003; 289:730-740

4. Cazeau S, Leclercq C, Lavergne T, et al., for the Multisite Stimulation In Cardiomyopathies (MUSTIC) Study Investigators. Effects of Multisite Biventricular Pacing in Patients With Heart Failure and Intraventricular Conduction Delay. *N Engl J Med.* 2001; 344:873-80

5. Garcia-Moran E, Mont L, Brugada J. Inappropriate tachycardia detection by a biventricular implantable cardioverter defibrillator. *Pacing Clin Electrophysiol* 2002; 25:123-124

6. Gras D, Leclercq C, Tang A, Bucknall C, et al. Cardiac resynchronization therapy in advanced heart failure the multicenter InSync clinical study. *Eur J Heart Fail* 2002; 4 311–320

7. Kühlkamp V. Initial experience with an implantable cardioverter-defibrillator incorporating cardiac resynchronization therapy. *J Am Coll Cardiol* 2002; 39:790-797

8. Schreieck J, Zrenner B, Kolb C, Ndrepepa G, Schmitt C. Inappropriate Shock Delivery Due to Ventricular Double Detection with a Biventricular Pacing Implantable Cardioverter Defibrillator. *Pacing Clin Electrophysiol* 2001; 24:1154–1157

9. St. John Sutton MG, Plappert T, Abraham WT, et al. Effect of cardiac resynchronization on left ventricular size and function in chronic heart failure. *Circulation* 2003; 107:1985-1990

10. Young JB, Abraham WT, Smith AL, Leon AR, Lieberman R, Wilkoff B, Canby RC, Schroeder JS, Liem LB, Hall S, Wheelan K for The Multicenter InSync ICD Randomized Clinical Evaluation (MIRACLE ICD) Trial Investigators. *JAMA* 2003; 289:2685-2694

11. Yu CM, Chau E, Sanderson JE, Fan K, Tang MO, Fung WH, Lin H, Kong SL, Lam YM, Hill MRS, Lau CP. Tissue Doppler Echocardiographic Evidence of Reverse Remodeling and Improved Synchronicity by Simultaneously Delaying Regional Contraction After Biventricular Pacing Therapy in Heart Failure. *Circulatio*n 2002; 105:438-445